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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,964	01/22/2004	Kevin Tait	SW-045AX	6339

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,964	TAIT, KEVIN	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-18* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/800,076.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Receipt

Receipt of Applicant's Response, filed 2/12/2007, in response to the Office Action mailed 10/12/2006, is acknowledged and has been entered. Claims 1 – 18 are pending.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 – 4, 6 – 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (US 3,236,735) for reasons set forth in the Office Action mailed 10/12/2006.

Applicant's arguments, see page 10 of the Response, with respect to the rejection of claims 1 – 4, 6 – 8, and 10 under 35 U.S.C. 102(b) as being anticipated by Brown have been fully considered but they are not persuasive. Applicant argues that Brown teaches a conventional x-ray contrast agent suitable for imaging the walls of the gastrointestinal system, and that the present claims are directed to a stool marker, whereby a normal contrast agent requires a highly disperse contrast agent, and that a stool marker must be flocculative, rather than dispersed. Applicant argues that the contrast agent of Brown is specifically designed to disperse barium sulfate in the intestine. This is not found persuasive because the limitations of claim 1, as currently written, wherein "IF the solid stool maker formulation is diluted to provide 0.5 to 3% w/v

barium sulfate, then from 0 to less than 0.035 N ionic dispersants are present... etc." do not impose any limitations on the claim (other than that composition comprises barium sulfate and a flocculant) because it is interpreted that such limitations are OPTIONAL because of the recitation of the term "if"). Furthermore, the limitation wherein the solid stool marker is diluted appears to be a product-by-process type limitation. Method steps (i.e. dilution) are not given patentable weight in composition claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Brown recites a solid composition comprising barium sulfate and a flocculant, Brown meets the claim. Regarding Applicant's arguments that Brown is directed to a conventional contrast agent, while the claims are directed to a stool marker, it is respectfully noted that the instant claims are composition claims, not method of use claims. The claims are examined only based on their components, not what happens after administration or the intended use (i.e. as a "stool marker" or "for dilution"). Whether or not the claimed compositions cause barium sulfate to be dispersed or flocculated is not relevant, only what is contained in the compositions may be used to distinguish over the prior art. As set forth in the previous action, a recitation

of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art to patentably distinguish the claimed invention from the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The recitation of "a solid stool marker which renders stool opaque" and "if said stool formulation is diluted" are "intended use" recitations which do not patentably distinguish.

Applicant also asserts that the composition of Brown requires ionic dispersants, while the claims recite that the compositions comprise from 0 to less than 0.35N ionic dispersants. This is not found persuasive because the claims only recite that IF the solid formulation is diluted to provide 0.5 to less than 3% w/v barium sulfate, then from 0 to less than 0.035N ionic dispersants are present" (i.e. there is no "normality" in a solid composition, and as noted above, it is interpreted that the dilution step is optional because of the recitation of "if".

Regarding the claimed limitation that wherein 0.25 g of the solid stool marker formulation is diluted with water to 50 ml and titrated against 3.0% ferrous sulfate at pH 5.0 – 5.5 has a flocculation resistance of less than 5 ml, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. The claims are limited only by descriptive language, and the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat.

App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 – 4, 6 – 8, and 10 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 3,236,735) in view of Queille (4,120,946) for reasons set forth in the Office Action mailed 10/12/2006.

Applicant's arguments, see page 14 of the Response, with respect to the rejection of claims 1 – 4, 6 – 8, and 10 – 16 under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Queille have been fully considered and they are persuasive in part. Applicant again contends that Brown fails to meet the present claims because of the presence of ionic dispersants. As noted above, this is not persuasive because it is interpreted that the dilution of the solid stool marker is an optional step which is not given patentable weight to distinguish over Brown. Applicant argues that Queille teaches no composition including a flocculant such as clay, and that the combination of Brown and Queille will be deficient with respect to avoidance of ionic dispersants and flocculation resistance as Brown is alone. This is persuasive with respect to claim 11, and the rejection over claim 11 is hereby withdrawn because the combination of Brown and Queille do not result in the formulation of claim 11. With regard to method claims 12 – 15, Applicant asserts that the step of "manipulating the

data to determine the portion of data due to marked stool" is not performed based on any teaching or suggestion. This is not found persuasive because the manipulation of data appears to be a mathematical transformation which is not given patentable weight, and it is considered that any imaging procedure requires manipulation of data in the process of taking measurements and producing an image.

Claims 1 –10 and 12 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 3,236,735) in view of Ruddy (5,466,440) and Weaver (3,935,099) for reasons set forth in the Office Action mailed 10/12/2006.

Applicant's arguments, see page 17 of the Response, with respect to the rejection of claims 1 –10 and 12 – 16 under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Ruddy and Weaver have been fully considered but they are not persuasive. Applicant argues that Ruddy's formulations include a polymeric surfactant and a smectite clay, which improve adhesion to the GI mucosa, in contrast with the presently claimed compositions that flocculate and mark the stool, and that Ruddy teaches that use bioadhesive surfactants (which are dispersants) with a view to stabilizing the suspension (i.e. to prevent flocculation). This is not found persuasive because the composition of Ruddy was used to show that barium sulfate having particle sizes within the claimed range and prepared via high shear is known in the art for imaging. Furthermore, it appears that the formulations of Ruddy do not require ionic dispersants. See column 3, lines 50 – 65: The compositions comprise barium sulfate, a bioadhesive surfactant, a clay and water in varying amounts. Column 4, line 1 indicates

a secondary stabilizer (i.e. ionic substances such as SLS, DOSS) may be used, but this does not appear to be a required material. The bioadhesive stabilizers which are required include poloxamers and other polymers (column 4, lines 18 – 25) which are not ionic. Applicant argues that Weaver is cited for the use of sonication but that Weaver is not in the field of imaging. It is further respectfully submitted that the limitation of claim 9, wherein the formulation is treated with high shear or sonication is a product by process limitation. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, the claim is met by Ruddy who teaches high shear processing for barium sulfate formulations.

Claims 1 – 4, 6 – 8, 10 and 12 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 3,236,735) in view of Kaufman (US 6,331,116) for reasons set forth in the Office Action mailed 10/12/2006.

Applicant's arguments, see page 19 of the Response, with respect to the rejection of claims 1 – 4, 6 – 8, 10 and 12 – 16 under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Kaufman have been fully considered but they are

not persuasive. Applicant argues that Kaufman is directed to a conventional contrast agent and does not cure the defect of Brown. This is not found persuasive because, as noted above, it is interpreted that the dilution of the solid stool marker (and thus the limitation regarding the amount of ionic dispersants present in solution) appears to be an optional step (i.e. "if) which is not given patentable weight to distinguish over Brown.

Response to Arguments

Applicant's arguments, filed 2/12/2007, see page 7 of the Response, with respect to the Double Patenting rejection over the claims of US 6,726,896 have been fully considered and are persuasive because of the restriction requirement in the parent case. The Double Patenting rejection has been withdrawn.

Applicant's arguments, see page 9 of the Response, with respect to the rejection under 35 U.S.C. 112, First Paragraph have been fully considered and are persuasive. The rejection of claim 1 under 35 U.S.C. 112, First Paragraph has been withdrawn as having been overcome by amendment.

Claim Objections

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1 – 10 and 12 – 18 stand rejected. Claim 11 is objected to as being dependent upon a rejected base claim but is otherwise free of the prior art. Although Applicant's arguments as set forth in the aforementioned Response have been fully considered, they are deemed unpersuasive. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER